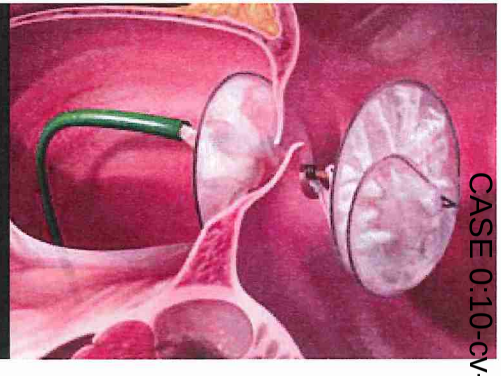
Exhibit 31

Training Manual

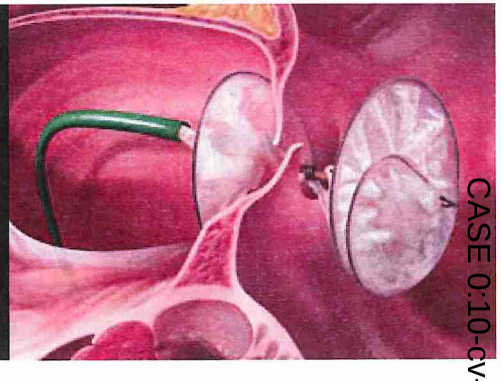
GORE HELEX SEPTAL OCCLUDER

CONTENTS



HELEX SEPTAL OCCLUDER GORE

HISTORY



1995-96	Prototype development
1997-98	Pre-clinical testing
1999	CE marked in June
2000	US Feasibility Study initiated in April
2001	US Pivotal Study initiated in March
2003	US Continued Access Study with hydrophilic-coated ePTFE initiated in May

Special thanks to the following cardiologists for input and guidance in the use of the GORE HELEX Septal Occluder:

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John Hess, M.D.
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Horst Sievert, M.D.
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Philippe Bonhoeffer, M.D.
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Sarah Badran, M.D.
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Frank Ing, M.D.
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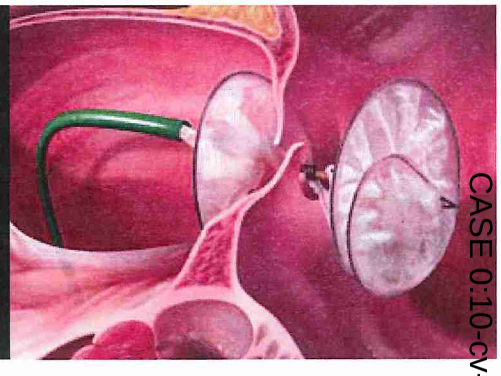
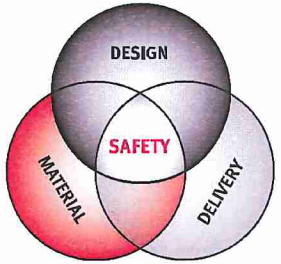
Kak Chen-Chan, M.D.
Michael deMoor, M.D.
Evan Zahn, M.D.
Collin Crowley, M.D.
Thomas Zellers, M.D.

FEATURES SUMMARY



Compliant Septal Occluder Design

- Circumferential nitinol support frame covered with an ePTFE membrane
- Conforms to anatomical contours of the septum
- Lies flat without bulky protrusion into the atria
- Exceptional wall apposition adapts to natural heart movement
- Compliant, atraumatic to surrounding cardiac structures, designed to avoid erosion and perforation
- Allows safe closure of defects with deficient anterosuperior rim



ePTFE Membrane Material

- ePTFE material performance is proven in over 13 million clinical implants
- Reduced thrombogenicity
- Controlled tissue response
- Biocompatible ePTFE material supports the formation of a functional intimal cell lining
- Microporous surface allows thin and firm tissue attachment without exuberant tissue formation
- Thin and strong ePTFE encapsulates the nitinol frame

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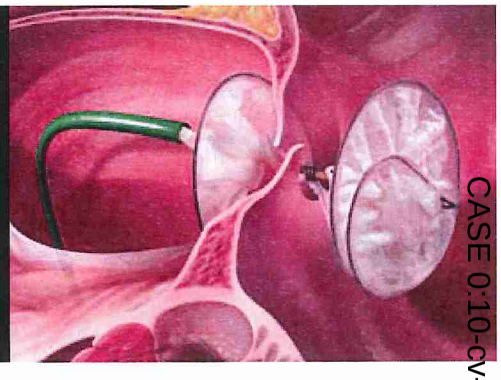
⚠ Attention,
See Instructions for Use

FEATURES SUMMARY



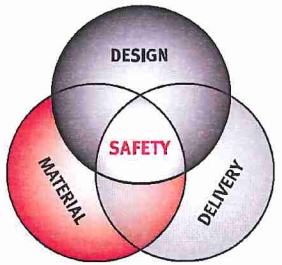
Complete Delivery System

Sheathless Delivery

- Simplicity, safety, accuracy
- Eliminates long transeptal sheaths and the risk of air embolization and perforation
- Pre-assembled Occluder for easy loading
- Pre-curved catheter for easy access to target defect
- Slotted guidewire port facilitates access across difficult multi-fenestrated defects and small PFOs

Controlled Repositioning and Retrieval

- Precise positioning for optimal Occluder placement
- Unique Retrieval Cord secures device even after lock release
- No need to compromise positioning or leave behind a suboptimal implant
- Soft Occluder easily recovered – even after complete release from the delivery system



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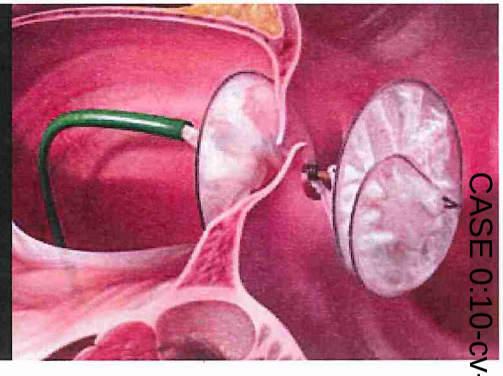
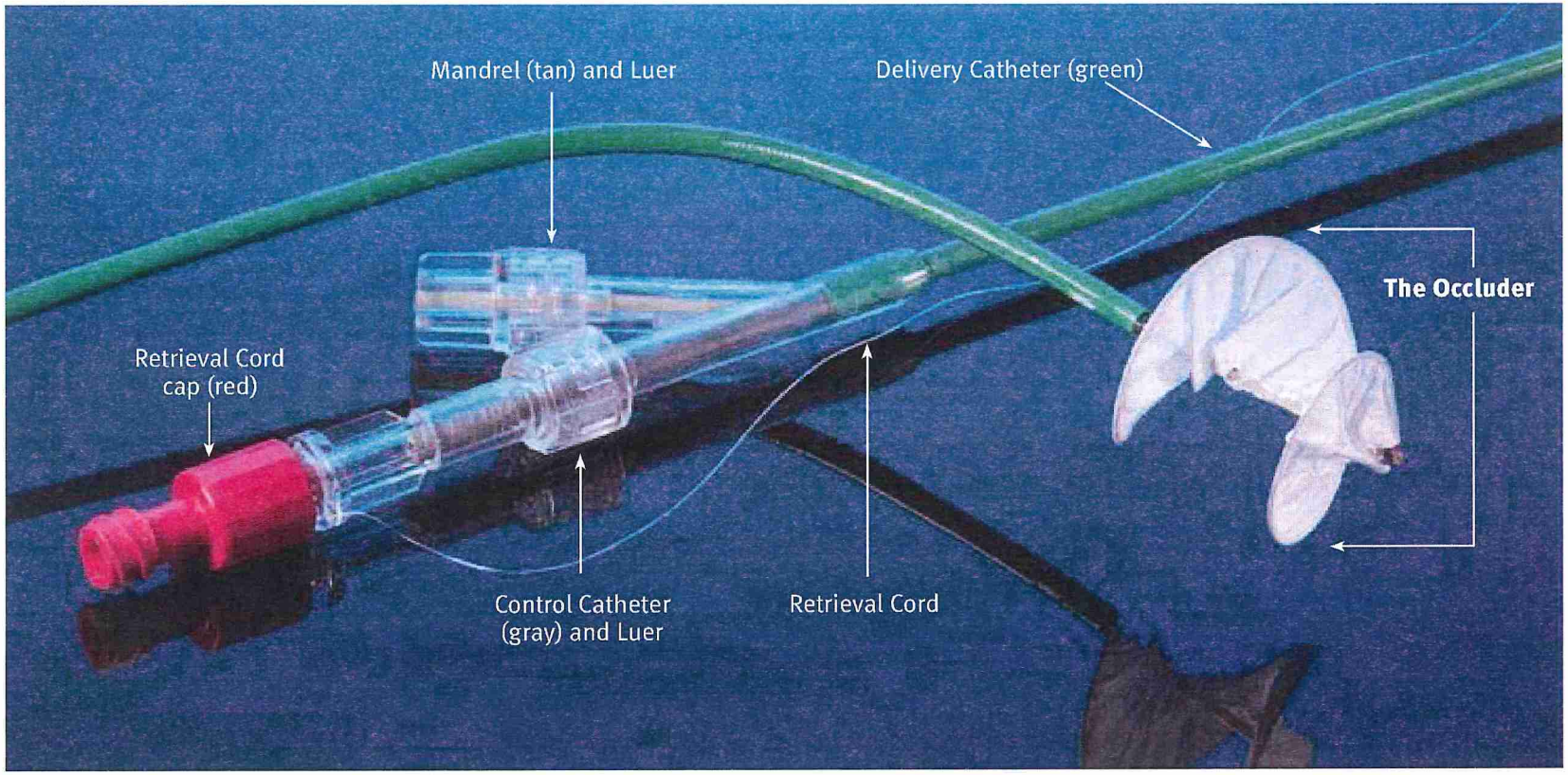
PRODUCT





GORE HELEX Septal Occluder

⚠ Attention,
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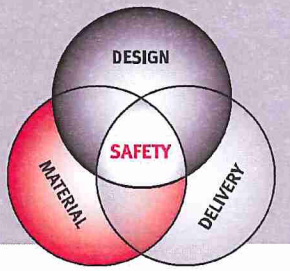
The GORE HELEX Septal Occluder



The GORE HELEX Septal Occluder is comprised of two circumferential nitinol support frames covered with an ePTFE membrane designed to conform to the anatomical contours of the septum. The ePTFE material provides a matrix that promotes tissue attachment, improving the security of the Occluder and reducing the potential for residual leakage. The sheathless delivery system eliminates long transseptal sheaths and their inherent risk of air embolization and perforation (Fig. C-1).

The GORE HELEX Septal Occluder is provided in five sizes, ranging from 15 mm to 35 mm, in 5 mm increments (Fig. C-2).

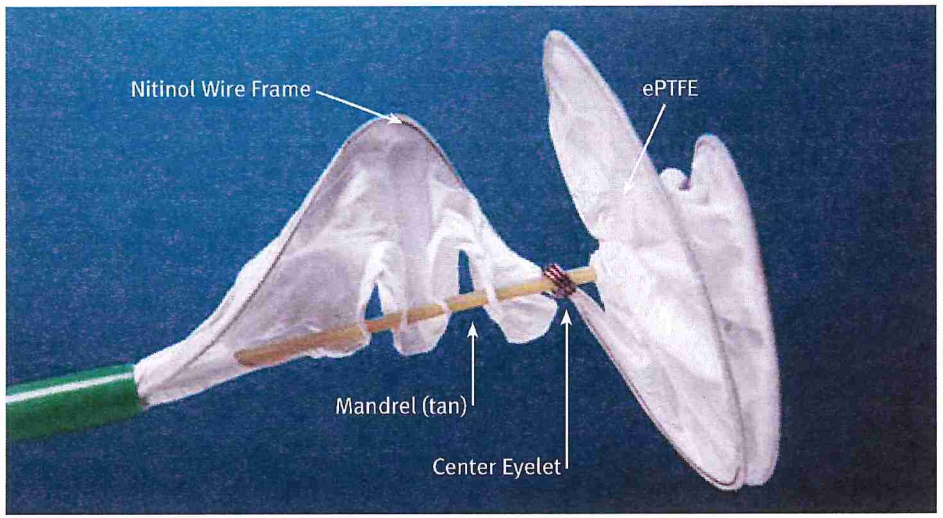
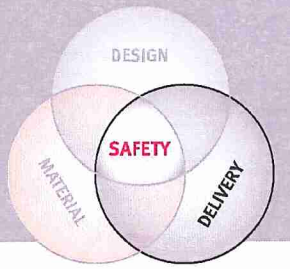


Figure C-1 –Occluder and Mandrel (tan)

Figure C-2 –Occluder diameters

Delivery System



Y-Arm

The "Y-Arm" of the GORE HELEX Septal Occluder simplifies deployment (Fig. C-3). The Control Catheter (gray) and Mandrel (tan) have only limited movement and must be locked in place at certain steps during device deployment.

At the distal end of the delivery system, the Mandrel (tan) is co-axial within the Delivery Catheter (green) and the Control Catheter (gray) (Fig. C-4). Midway along the delivery system, the Mandrel (tan) bifurcates out at the Control Catheter (gray) lumen, to provide separate control "handles" for the operator.

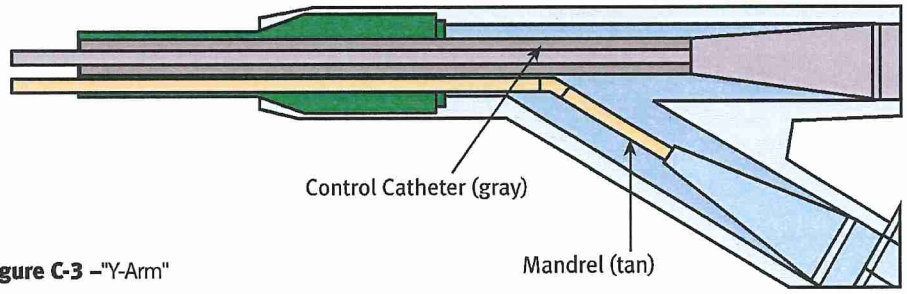
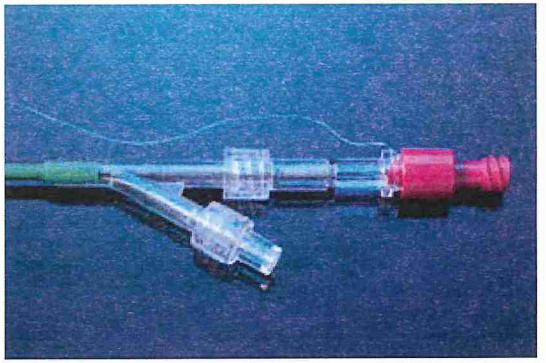


Figure C-3 –"Y-Arm"



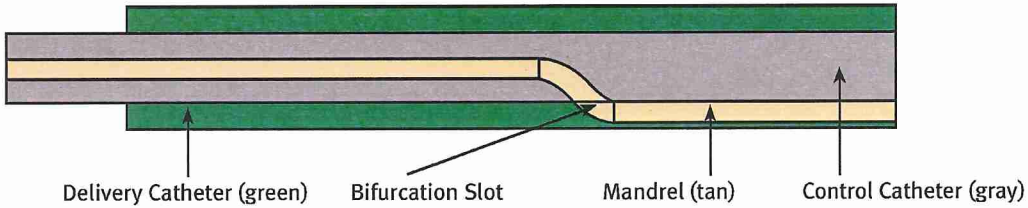
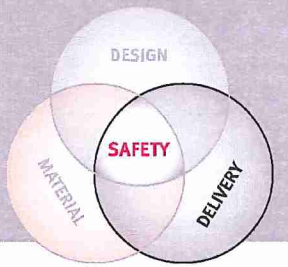


Figure C-4 –Longitudinal section of component bifurcation

⚠ Attention,
See Instructions for Use

Delivery System



Complete delivery system is used for deployment, repositioning and retrieval.

Delivery Catheter (green)

- Contains elongated Occluder
- 10 Fr diameter
- Perforated to allow delivery over 0.035" wire (Fig. C-5)
- Pre-shaped catheter positions the Occluder across the defect (Fig. C-6)
- Working length – 75 cm

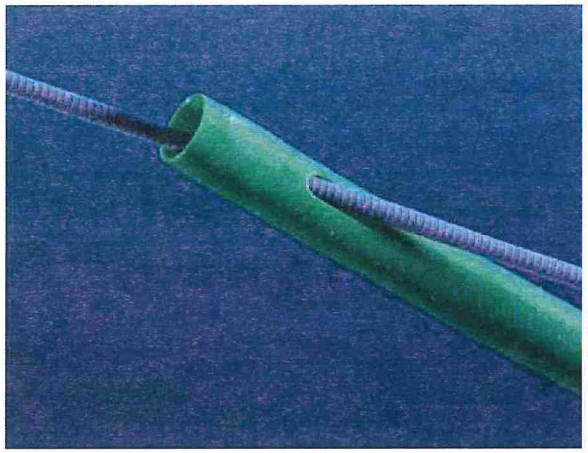


Figure C-5 –Guidewire slot with 0.035" guidewire in place

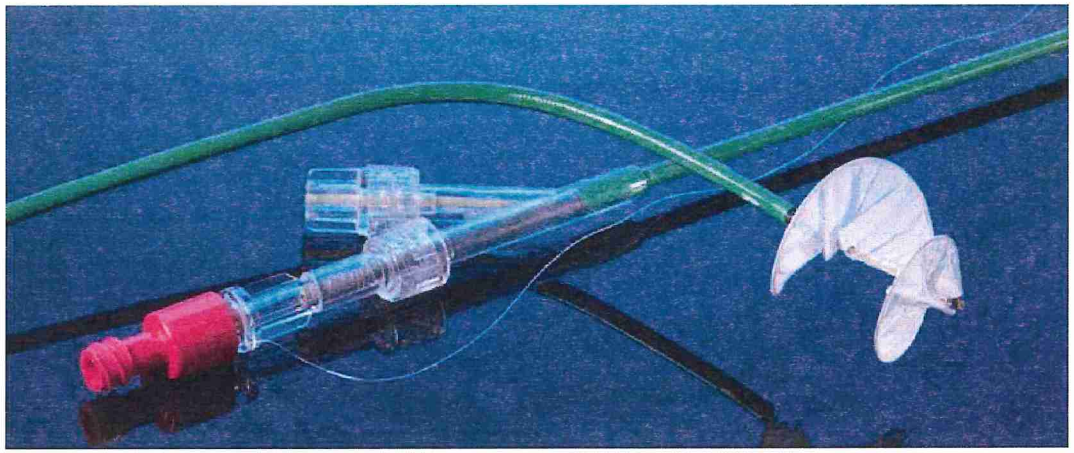


Figure C-6 –GORE HELEX Septal Occluder

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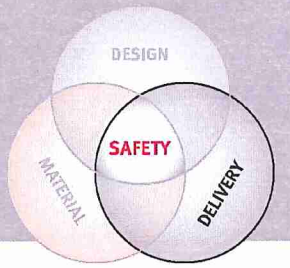
Delivery System



Control Catheter (gray)

- Includes Retrieval Cord and Retrieval Cord cap (red) (Fig. C-7)
  - Retrieval Cord holds Occluder to delivery system after lock release (Fig. C-8)
  - Can be used to unlock and retrieve Occluder after lock release if necessary (Fig. C-8)

- "D" shaped catheter and Mandrel (tan) lumen prevents rotation of components (Fig. C-9)
  - Separate Mandrel and Retrieval Cord lumens to prevent entanglement
  - Slotted tip allows lock loop to consistently deploy through the side of the catheter, reducing disc separation during lock release

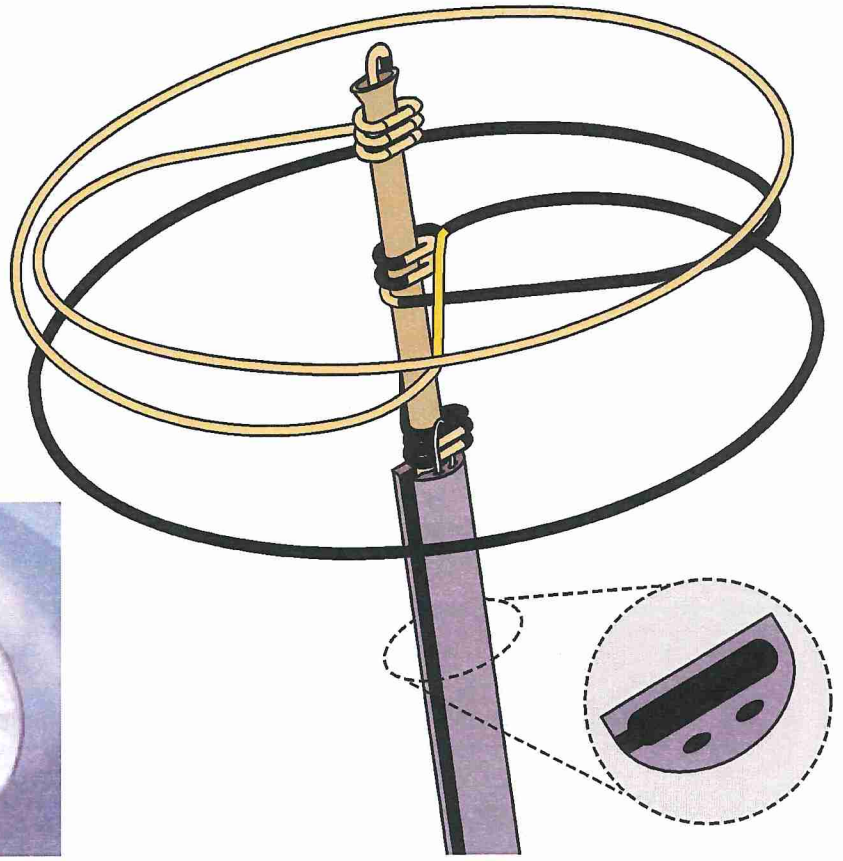


Figure C-9 –Occluder and cross-section of Control Catheter (gray)

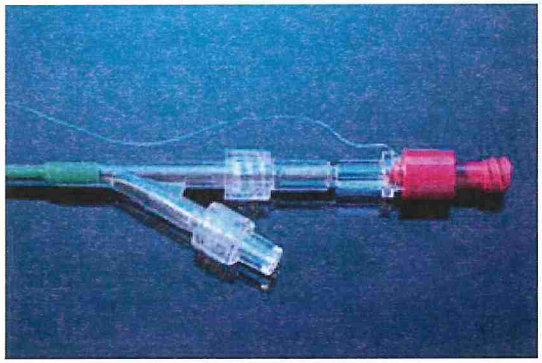


Figure C-7 –Retrieval Cord cap (red) secures end of Retrieval Cord to Control Catheter (gray)

Figure C-8 –Retrieval Cord looped through the proximal eyelet

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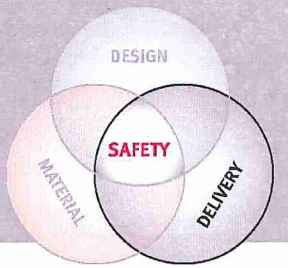
Delivery System



Mandrel (tan)

- Controls configuration of the Occluder
- Retains the integral locking mechanism until release
- Pulling gently on the Mandrel (tan) configures the Occluder into a circular shape

During assembly, the three eyelets and the ePTFE membrane perforations are threaded onto the Mandrel (tan). The locking loop is straightened and placed within the lumen of the Mandrel (tan). The Mandrel tip is flared to retain the eyelets until lock release (Fig. C-10).

Figure C-10 –Mandrel (tan) with flared tip

Delivery System

In Figure C-11, the Occluder is shown as it would appear prior to lock release and prior to loading the Occluder into the delivery system. The Retrieval Cord holds the right atrial eyelet of the Occluder to the tip of the Control Catheter (gray). The locking loop is held straight within the Mandrel (tan).

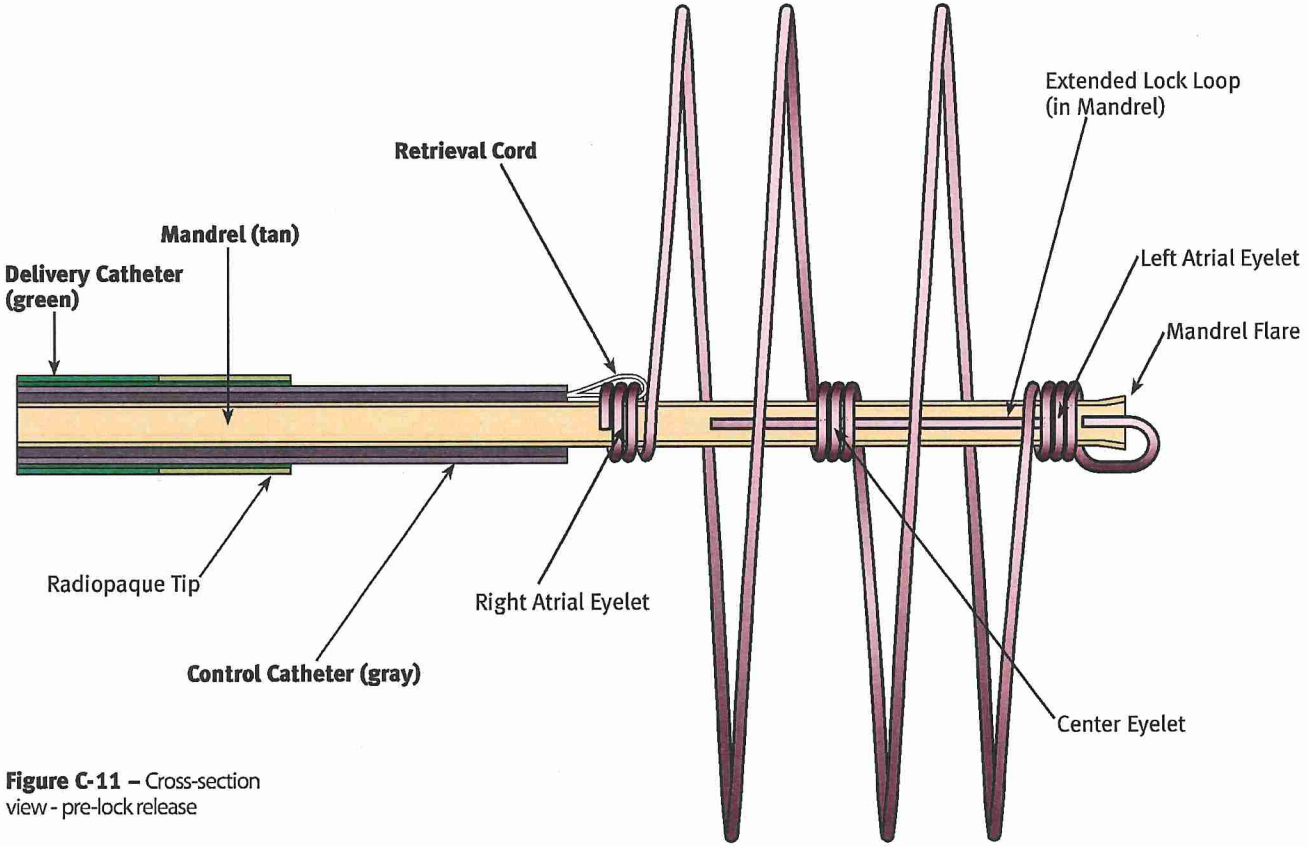


Figure C-11 – Cross-section view - pre-lock release

Attention, See Instructions for Use

Delivery System

A firm and quick pull on the Mandrel (tan) luer pulls the Mandrel tip through the three eyelets and allows the locking loop to deploy through the slot in the Control Catheter (gray) (Figs C-11 and C-12).

In Figure C-12, the Occluder is shown following lock release. The three eyelets are held closely together. The Mandrel (tan) has been withdrawn into the Control Catheter (gray), allowing the lock loop to form through the slot at the tip of the Control Catheter (gray).

Once locked, the Occluder is still attached to the tip of the Control Catheter (gray) by the Retrieval Cord.

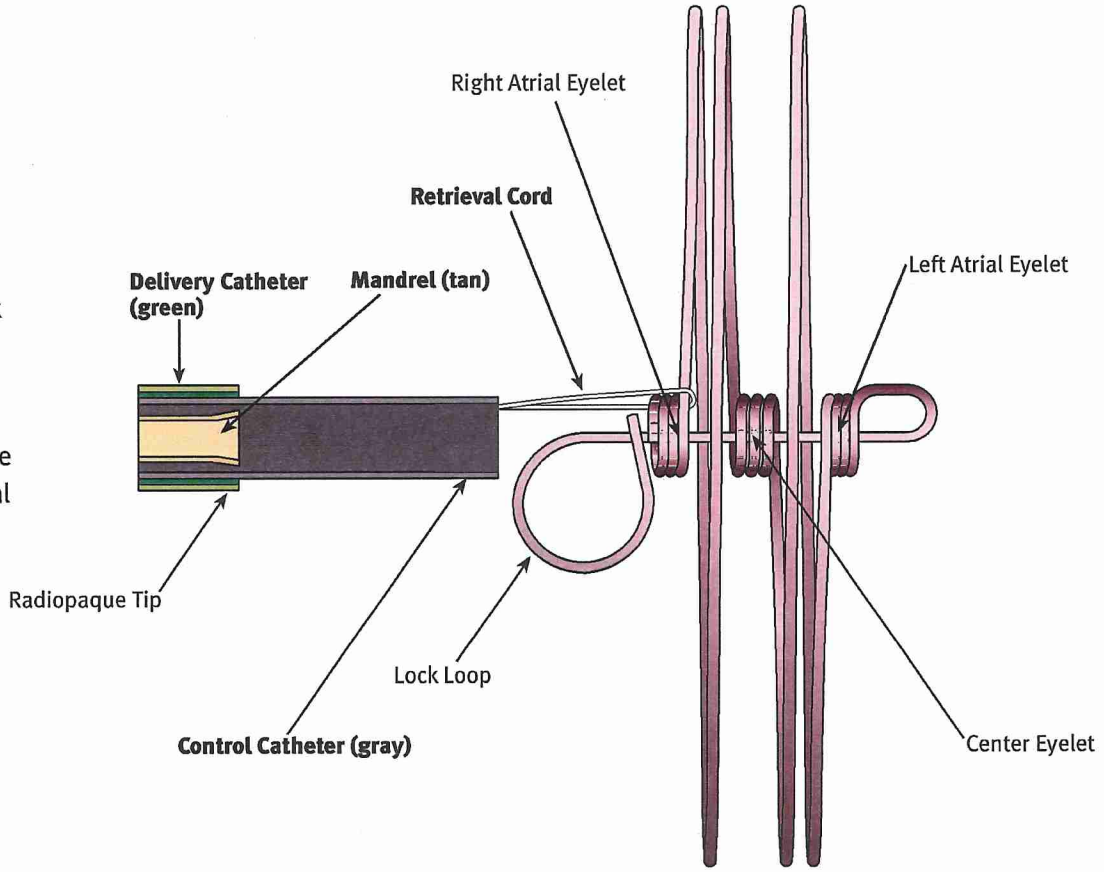
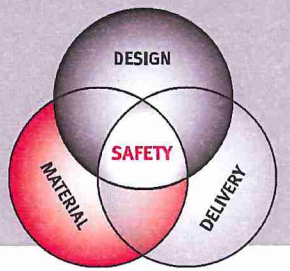


Figure C-12 –Cross-section view - locked

Attention, See Instructions for Use

Indications/Contraindications



INDICATIONS/INTENDED USE

The GORE HELEX Septal Occluder is a permanently implanted prosthesis indicated for the transcatheter closure of Atrial Septal Defects (ASDs) within the oval fossa (e.g. Secundum ASD, PFO).

CONTRAINDICATIONS

- The GORE HELEX Septal Occluder is contraindicated for use in patients with a septal wall thickness that would result in Occluder rim spacing of greater than one-half the labeled Occluder diameter.
- Do not use the device in ASDs that are located eccentrically on the septum (e.g., Sinus Venosus ASD and Ostium Primum ASD).
- There must be adequate room in the atrial chamber to allow the right and left atrial discs to lie flat against the atrial septum, without interference with critical cardiac structures. Do not place the device in a position that causes impingement on the mitral valve leaflets, the ostia of the pulmonary veins, coronary sinus, or other critical cardiac features.
- Do not use the GORE HELEX Septal Occluder in patients with the following conditions:
  - sepsis
  - intra-cardiac thrombus
  - venous access vessel thrombus or blockage
  - contraindication to antiplatelet and/or anticoagulation therapy

Footnote:
*Indicated for closure of ASD and PFO in Europe. Clinical trial underway in the U.S., indicated for ASD only.

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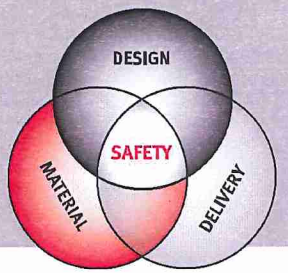
Equipment Considerations

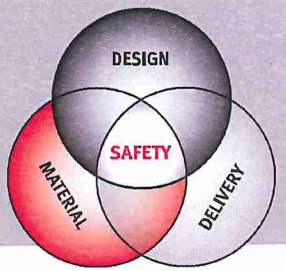


Facilities implanting the GORE HELEX Septal Occluder should have an interventional cardiac catheterization laboratory equipped with:

- High resolution fluoroscopic imaging equipment.
- Transesophageal Echocardiography (TEE) or Intracardiac Echocardiography equipment with color flow doppler capabilities.
- A standard range of catheterization supplies including 10 Fr and larger introducer sheaths, guidewires, and sizing balloons.
- Should the emergency retrieval of an embolized device become necessary, larger, Mullins-type sheaths, snare catheters (35 mm will capture all sizes) or retrieval baskets should be available.

This product is intended for use by physicians experienced with interventional cardiology procedures and trained in the use of the GORE HELEX Septal Occluder.

Choosing the Optimal Size

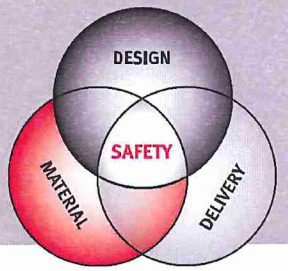


Evaluate the defect and the atrial dimensions using TEE and fluoroscopy.

- Determine defect size using a sizing balloon across the defect. Inflate the balloon until flow stops through the defect as determined by Doppler ultrasound or until the length of the tissue tunnel can be measured.
- Evaluate the defect location and atrial chamber size by TEE, ICE and/or color flow Doppler measurement, confirming that there is adequate space to accommodate the selected Occluder size without impinging on adjacent cardiac structures (e.g., A-V valves, ostia of the pulmonary veins, coronary sinus).
  - There must be adequate room in the atrial chambers to allow the right and left atrial discs to rest flat against the septum with disc spacing equal to the septal thickness.
- The recommended GORE HELEX Septal Occluder size should provide a nominal 2:1 Occluder diameter-to-defect diameter ratio. Deploying the Occluder in cases where the Occluder diameter-to-defect diameter ratio <1.6:1 increases the risk of device embolization. Ensure that adequate rim to retain the Occluder is present around approximately 75% of the defect.
  - An Occluder that pulls through the defect during disc conformation may be too small and should be removed and replaced with a larger size if the chamber dimensions are adequate.

The GORE HELEX Septal Occluder is available in diameters of 15, 20, 25, 30, and 35 mm, allowing closure of defects up to 22 mm.

Patient Considerations



The patient must be able to accommodate a 10 Fr introducer sheath.

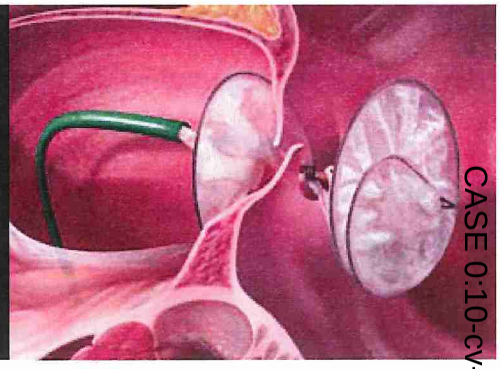
Activated Clotting Time (ACT) should be maintained at 2x baseline or greater throughout the procedure.

Standard and accepted post-procedural antiplatelet and antibiotic therapy should be employed.

Refer to the GORE HELEX Septal Occluder Instructions for Use for patient warnings.

⚠ Attention,
See Instructions for Use

DEPLOYMENT INSTRUCTIONS



The following pages describe the deployment of the GORE HELEX Septal Occluder.
Three major points are addressed:

Loading/Flushing

Disc Formation

Lock Release

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Loading/Flushing

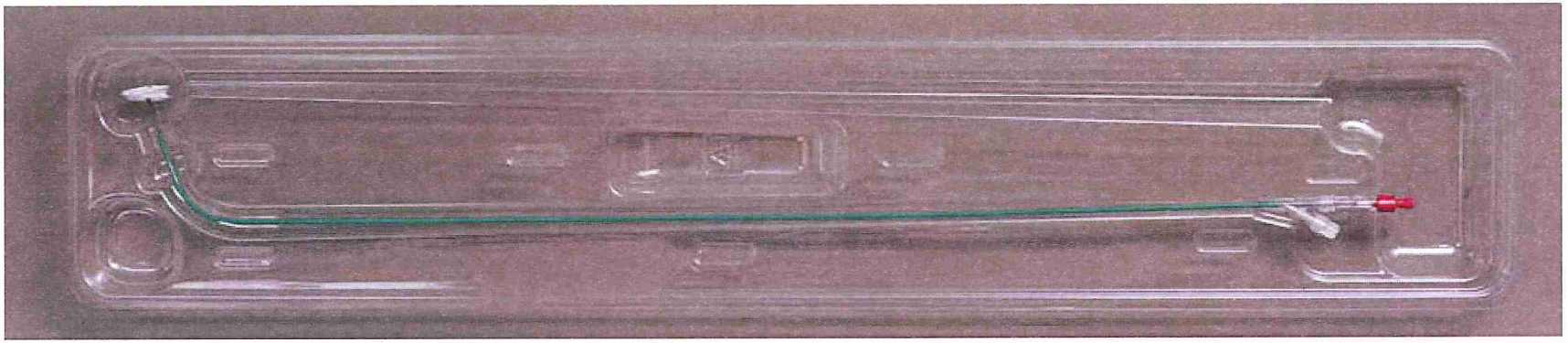


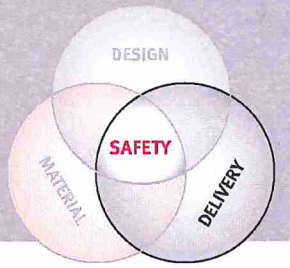
Figure D-1 –The GORE HELEX Septal Occluder Delivery System and Tray

The GORE HELEX Septal Occluder is provided in a sterile package ready to load. Prior to loading, the disc is fully formed and both the Control Catheter (gray) luer and the Mandrel (tan) luer are locked. The Retrieval Cord is held tightly by the Retrieval Cord cap (red) (Fig. D-1).

To begin the loading process, submerge the GORE HELEX Septal Occluder in heparinized saline. Keep the delivery system straight during loading.

Fill a syringe (12-50 ml) with heparinized saline, attach it to the Retrieval Cord cap (red) and flush to fill the system.

Loading/Flushing



- To begin loading, assure the Mandrel (tan) luer is locked. Grasp the "Y-Arm" and loosen the Control Catheter (gray) luer (Fig. D-2). With the right hand, gently pull (retract) the Control Catheter (gray) (Fig. D-3). The Mandrel hub is locked, holding the Mandrel (tan) in place. The Occluder will be easily drawn into the catheter.

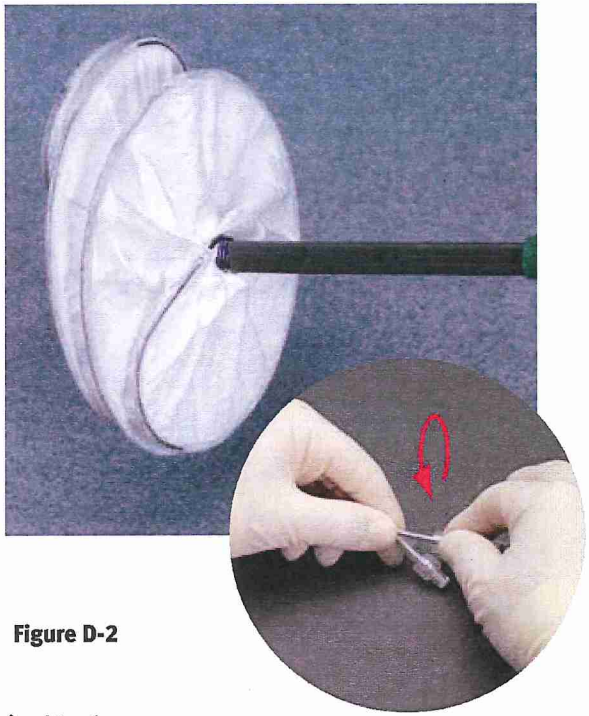


Figure D-2

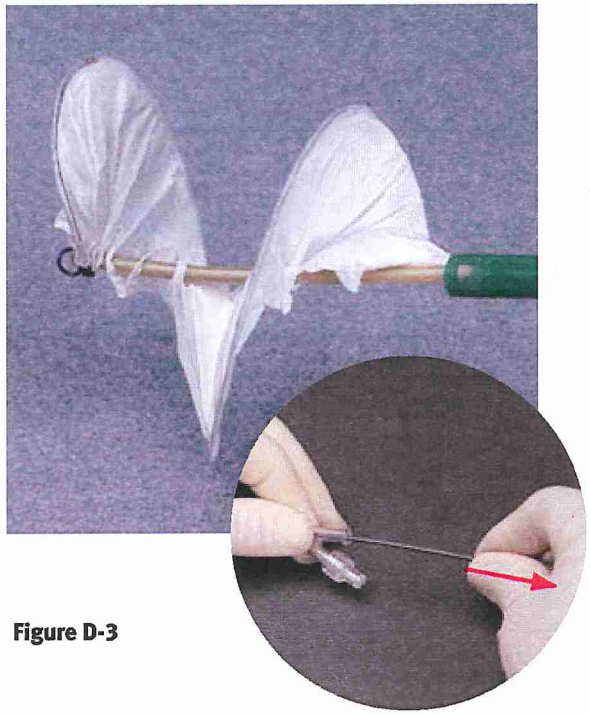


Figure D-3

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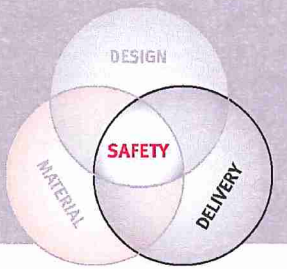
Loading/Flushing



- Once the Mandrel (tan) tip and Occluder begin to bow, (Fig. D-4), loosen the Mandrel (tan) luer.
- Grasp the Control Catheter (gray) and continue to pull until the entire Occluder is inside the Delivery Catheter (green) (Fig. D-5).
- Once the entire Occluder is loaded into the Delivery Catheter (green), reload the syringe with heparinized saline, and flush vigorously.
- Leave the syringe attached as the delivery system is moved to the table; flush again just prior to inserting the catheter into the sheath.

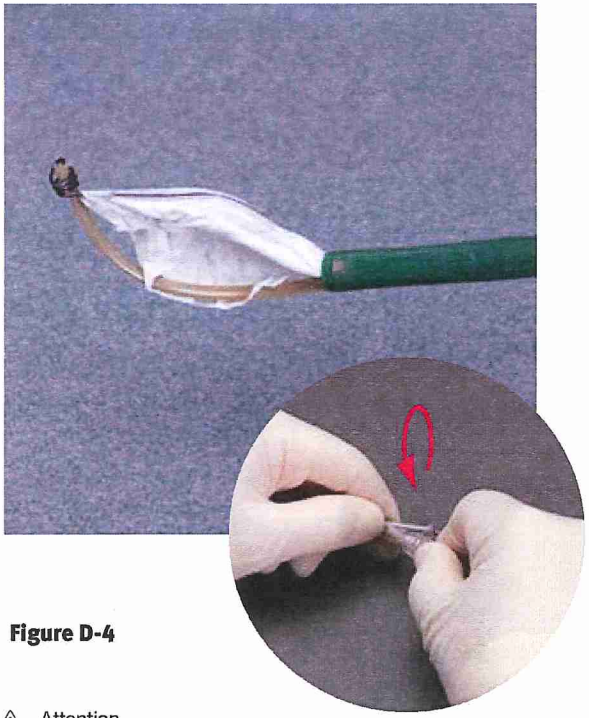


Figure D-4

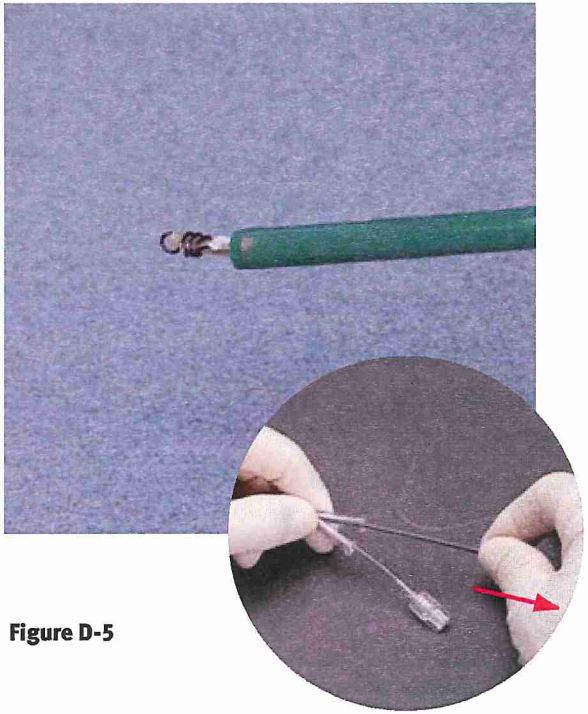
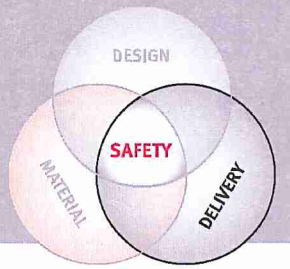


Figure D-5

⚠ Attention, See Instructions for Use

WLG0069901

Advancing the System to the Defect



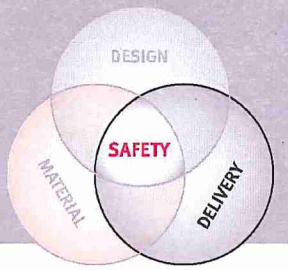
The GORE HELEX Septal Occluder has been designed as a self-contained delivery system and may be advanced across many defects directly.

Physicians may choose to access the defect with a guidewire or a long sheath in order to select a particular fenestration or save time accessing a small tunnel.

The GORE HELEX Septal Occluder delivery system can be advanced over a wire using the perforation provided. In that case, a larger introducer sheath > 12 Fr must be employed.

If a long sheath is employed, it must be at least 10 Fr and less than 75 cm in length.

Deployment



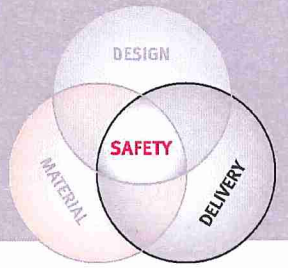
When ready to deploy, confirm by echocardiography that the tip of the catheter is across the defect. The delivery system will appear as in the photo below (Fig. D-7).

- Both luers are unlocked.
- The Control Catheter (gray) is retracted sufficiently to bring the entire Occluder within the Delivery Catheter (green).
- 3 to 4 cm of the Mandrel (tan) is exposed between the luer and hub.

Figure D-7

⚠ Attention, See Instructions for Use

Left Atrial Disc Deployment

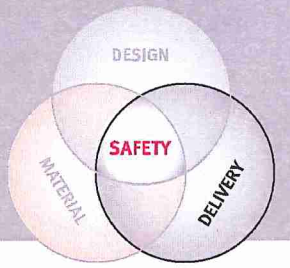


To begin deployment of the left atrial disc, grasp the "Y-Arm" in the left hand. All delivery motions of the Occluder should be observed on fluoroscopy with the intra atrial position confirmed by echocardiography.

- Push the Control Catheter (gray) to advance (Fig. D-8a, next page).
  - Notice that the Mandrel (tan) moves as the Control Catheter (gray) is pushed.
- Continue pushing lightly until the Mandrel (tan) luer engages the "Y-Arm".
- Pinch (hold) the Control Catheter (gray) with the left thumb and forefinger to hold Occluder in position (Fig. D-8b, next page).
- Pull the Mandrel (tan) luer gently to form the disc (Fig. D-8c, next page).
  - The operator will feel a light tactile “stopping” sensation.
  - Avoid pulling left atrial eyelet against the Delivery Catheter (green) tip.
- Repeat the “Push/Pinch/Pull” sequence until the left atrial disc is formed to complete the deployment.

⚠ Attention, See Instructions for Use

Left Atrial Disc Deployment



Push

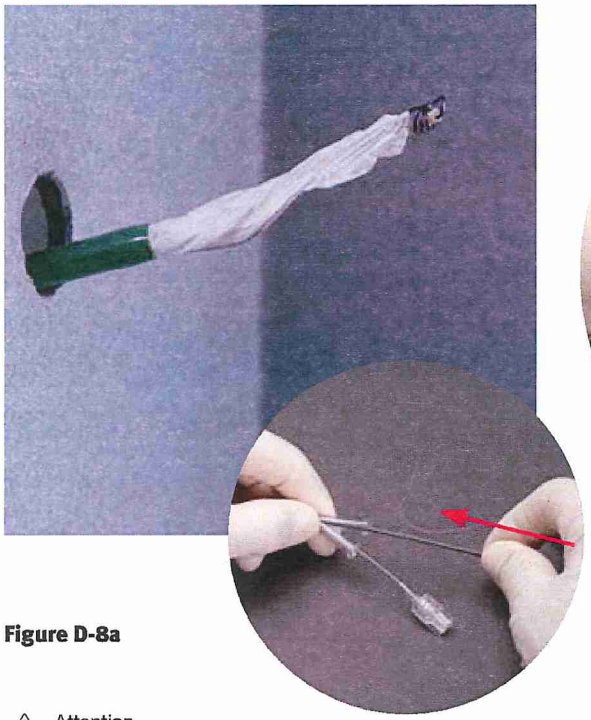


Figure D-8a

Pinch

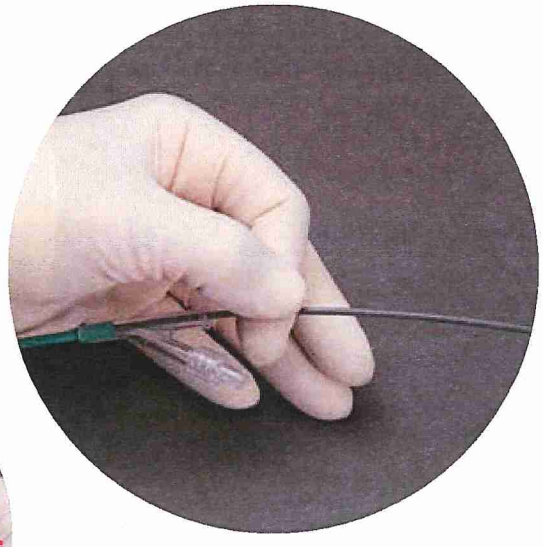


Figure D-8b

Pull

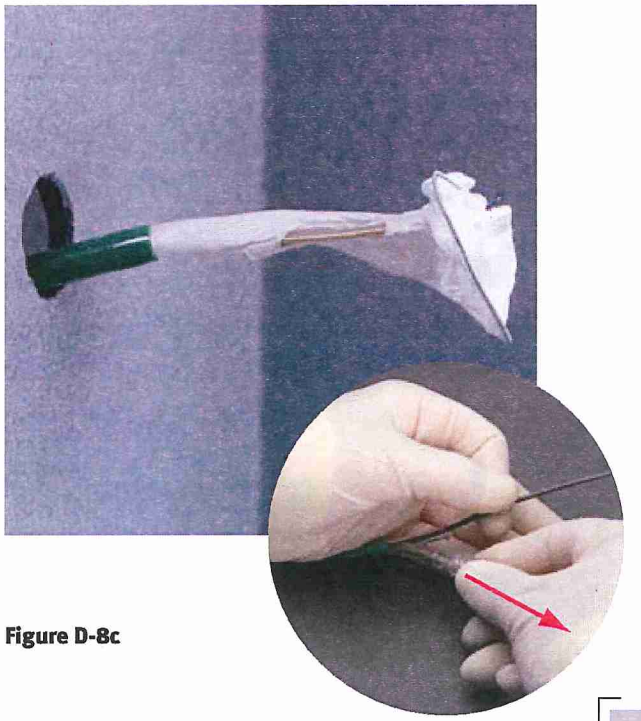
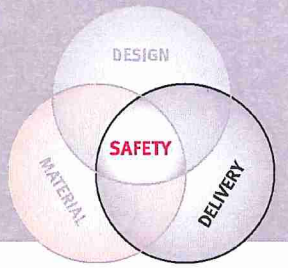


Figure D-8c

⚠ Attention,
See Instructions for Use

WLG0069905

Transition - Left to Right



Once the central eyelet exits the catheter tip, the operator will prepare to appose the formed left atrial disc against the septum.

- Pull lightly on Mandrel (tan) to flatten left atrial disc (Fig. D-10a).
- Pull entire delivery system gently to appose the left atrial disc to the septum (Fig. D-10b).
  - Confirm contact with the septum on echocardiography.
  - Do not pull firmly against the septum.
- Hold Control Catheter (gray) and pull the Delivery Catheter (green) gently until the "Y-Arm" contacts the Mandrel (tan) luer to prepare for right atrial disc deployment.
- Tighten the Mandrel (tan) luer (Fig. D-10c).

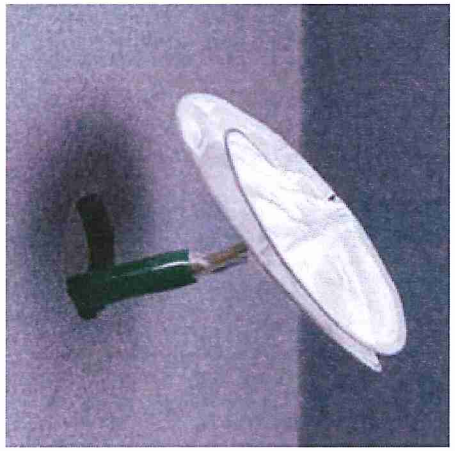


Figure D-10a –Left disc formation complete, formed left disc presented to septum

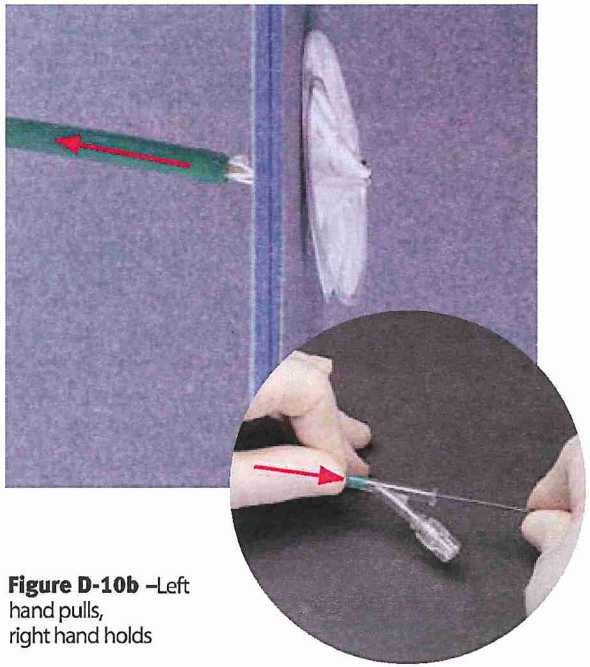


Figure D-10b –Left hand pulls, right hand holds

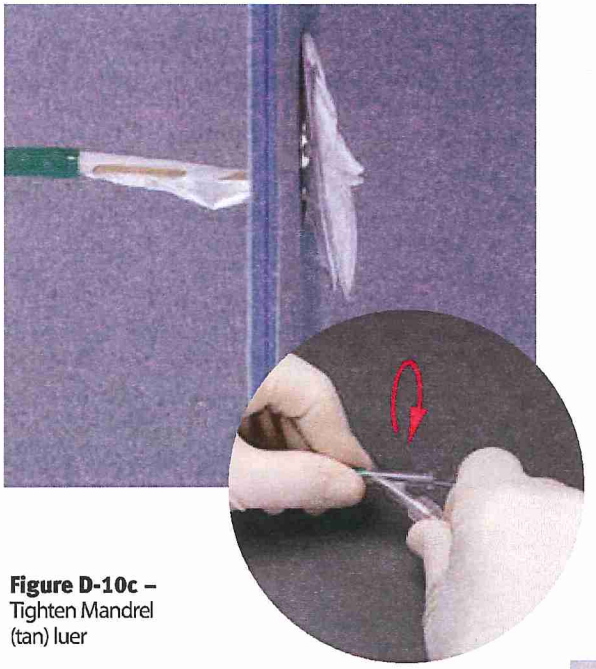
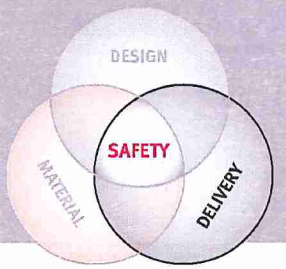


Figure D-10c – Tighten Mandrel (tan) luer

Attention, See Instructions for Use

WLG00669906

Right Atrial Disc Deployment



To deliver the right atrial disc:

- Hold the Delivery Catheter (green) in the left hand to stabilize the device against the septum.
- Push the Control Catheter (gray) smoothly with the right hand to form the right atrial disc.
- Tighten the Control Catheter (gray) luer.

The Occluder is now fully formed and prepared for lock release.

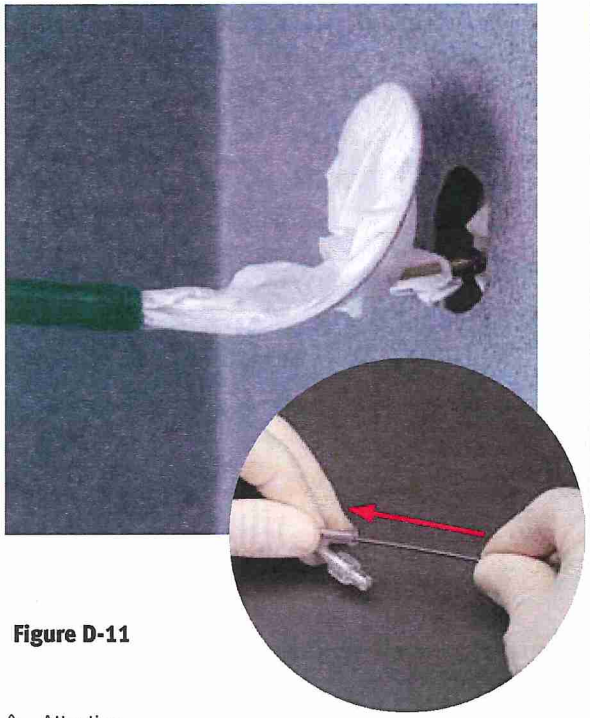


Figure D-11

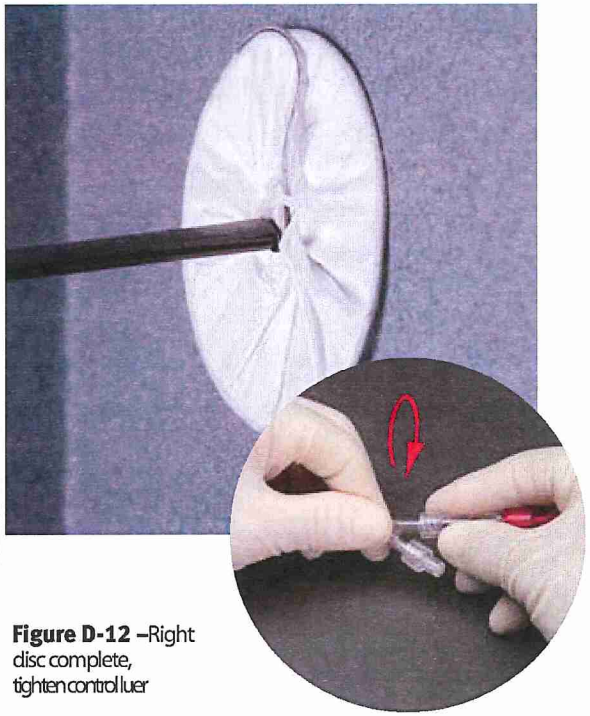


Figure D-12 –Right disc complete, tighten control luer

⚠ Attention, See Instructions for Use

WLG00699907

Lock Release

When appropriate, confirm position of the device on echocardiography.

- Remove the Retrieval Cord cap (red) and assure that the retrieval cord is free (Fig. D-13).
- Hold the "Y-Arm" with left hand to prepare for lock release.
- Loosen Mandrel (tan) luer (Fig. D-14).
- Pull the Mandrel (tan) firmly and quickly with right hand to release the lock (Fig. D-15).
  - Lock loop deploys through slotted tip while the Occluder is held in position between the tip of the Control Catheter (gray) and the flare on the Mandrel (tan) tip.

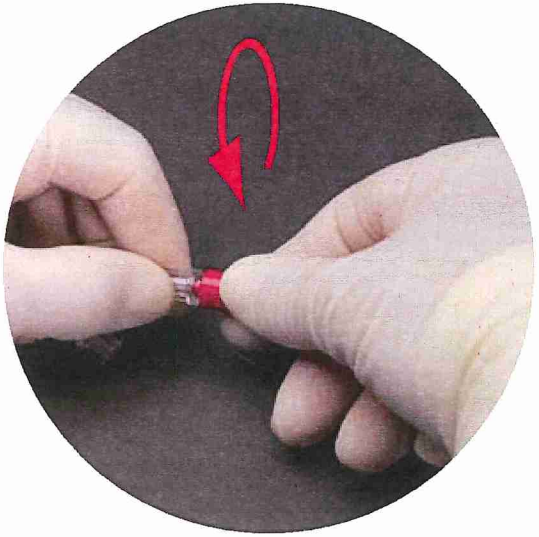


Figure D-13 –Remove Retrieval Cord cap (red)

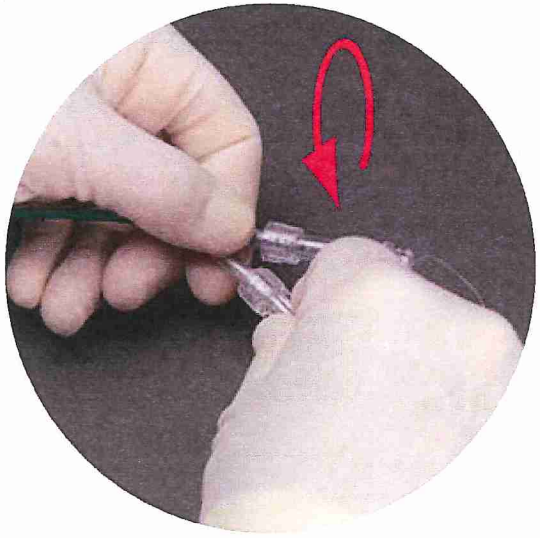


Figure D-14 –Loosen Mandrel (tan) luer

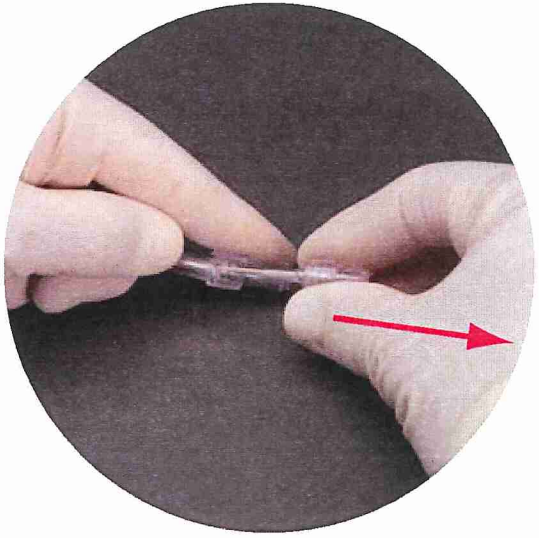


Figure D-15 –Quick, firm pull on the Mandrel (tan) to lock

Attention, See Instructions for Use

Delivery System Removal

When satisfied with Occluder position, the delivery system can be removed.

- Ensure that the Retrieval Cord cap (red) has been removed.
  - Retrieval Cord is free on one end and looped through the right atrial eyelet.
- Pull entire system until catheter and cord exit the hemostatic valve.
  - Dedicated Retrieval Cord lumen prevents tangling with other components.

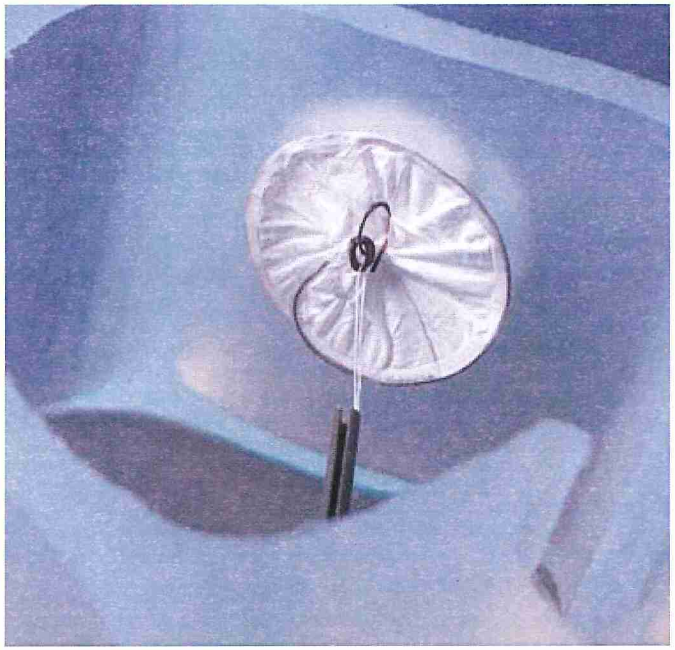
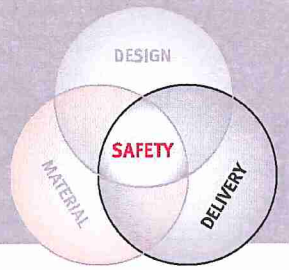


Figure D-16

⚠ Attention,
See Instructions for Use

WLG0069909

Device Retrieval



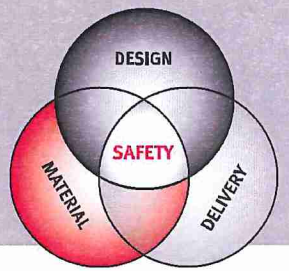
In the event of sub-optimal deployment, the Occluder may be removed.

- Gently pull on Retrieval Cord to bring delivery system back into contact with the Occluder.
- Replace and tighten Retrieval Cord cap (red) to secure the Retrieval Cord.
- Loosen Control Catheter (gray) luer.
- Pull Control Catheter (gray) back into the Delivery Catheter (green).
  - Keep tip of Delivery Catheter (green) away from lock loop.
- Continue to unlock the Occluder until free of the septum.
- Once free, pull entire system to groin and complete removal by pulling through the sheath.

As long as the Occluder remains seated in the septum, the device will unlock and can be drawn into the Delivery Catheter (green). The operator must exercise care that the Delivery Catheter (green) is withdrawn sufficiently to allow the locking loop to fully extend (Figs. E-2 and E-3).

Once the Occluder is free of the septum, the locking loop will present higher resistance and could cause the Retrieval Cord to break. The operator is cautioned to draw the entire Occluder/delivery system assembly back to the introducer sheath before completing device retrieval.

Review



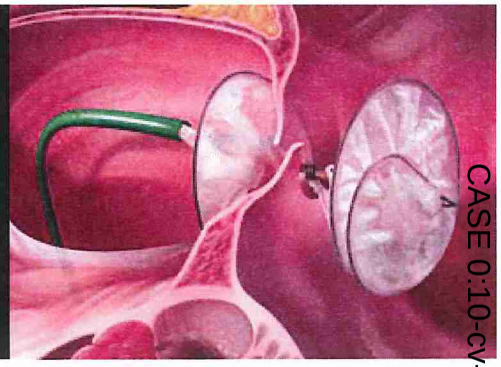
ALWAYS

- Use a light touch
- Move one component at a time
- Lock the Mandrel (tan) luer at completion of left atrial disc
- Lock Control Catheter (gray) luer at completion of right atrial disc
- Make smooth transition from left atrial disc to right atrial disc
  - Appose left atrial disc gently to left septum
  - Hold Control Catheter (gray)
  - Pull Delivery Catheter (green) to prepare for right atrial disc deployment

NEVER

- Pull the left atrial eyelet against the Delivery Catheter (green)
  - Premature lock may result
- Pull the left atrial disc firmly against the septum
  - Premature lock may result
- *Never* . . . push the Mandrel (tan)

TIPS FOR SUCCESS



The GORE HELEX Septal Occluder is a compliant device that quickly forms to the shape of the heart, reducing the potential for erosion through delicate tissues. Consequently, the Occluder can be positioned to close some complex defects, such as those with deficient anteriosuperior rims.

Although the GORE HELEX Septal Occluder is easy to deploy, there is a learning curve associated with achieving successful deployment.

The following sections elaborate on the Occluder design and describe some of the techniques that cardiologists have found useful to improve defect closure and take advantage of the unique characteristics of this device. These discussions will point out some of the more common issues a cardiologist may encounter during early use of the GORE HELEX Septal Occluder.

Repositioning

The GORE HELEX Septal Occluder can be precisely positioned and repositioned to create optimal Occluder placement. After lock release, the unique retrieval cord secures the device until the position is satsifactory. In most cases, only the right atrial disc must be drawn back into the Delivery Catheter (green) and redeployed to improve device position. Simply keep the Mandrel (tan) luer locked, pull the Control Catheter (gray) to withdraw the Occluder and push the Control Catheter to redeploy.

If the left atrial disc must be brought back into the catheter, the operator may experience higher than normal friction, resulting in premature deployment or Mandrel (tan) kinking. In some fluoroscopic planes, the operator may notice a bend in the locking loop (Fig. E-1). If such a condition should occur, the operator should remove the device from the patient and utilize a new device.

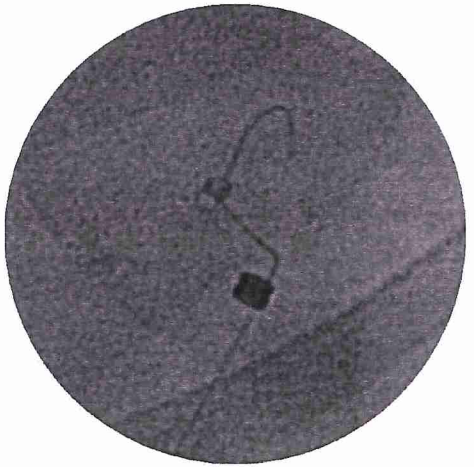
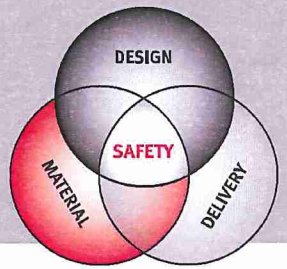


Figure E-1 –Bent locking loop

Emergency Recapture/Embolization



If at any time the Control Catheter (gray) can be pulled without corresponding movement of the Occluder, either during repositioning or following lock release, the operator should suspect a broken or lost Retrieval Cord. The cause may be simple, such as a loose Retrieval Cord cap (red), or the operator may have exerted more force on the cord than it is designed to handle.

If the device is free of the delivery system, interventional retrieval techniques should be employed (snares, retrieval baskets). In most cases, the Occluder can be unlocked and retrieved using a snare. Use a 10 Fr or larger long sheath, placed close to the device (35 mm) (Figs. E-2 and E-3). Snaring any portion of the device will collapse and unlock the Occluder safely.

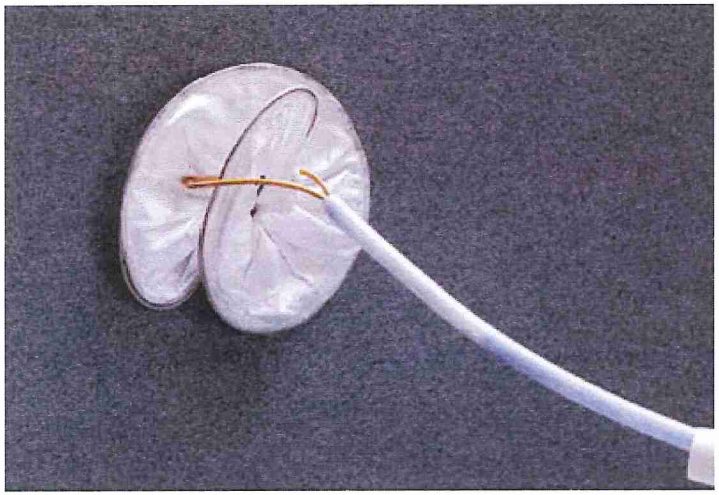


Figure E-2

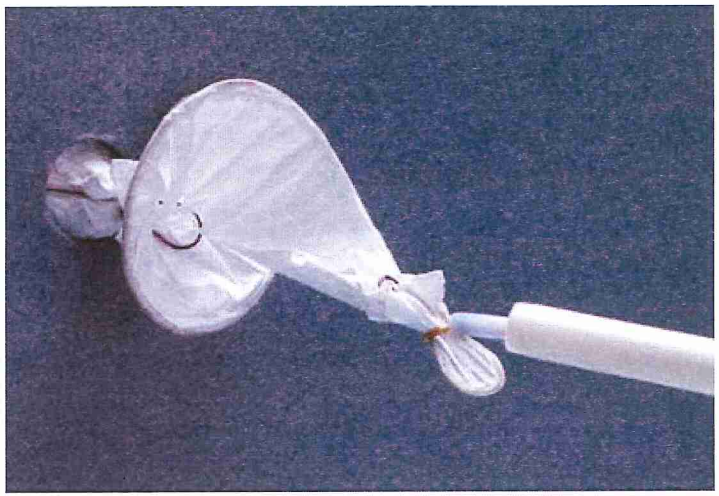
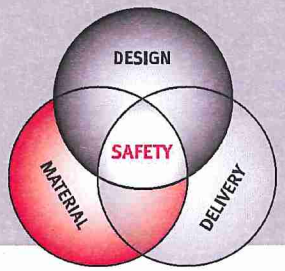


Figure E-3

Fluoroscopic Appearance



When deployed in a model having uniform dimensions, the Occluder appears planar and parallel (Fig. E-4). Notice that from the center eyelet, the two radial arms are placed on opposite sides of the septum, the lock mechanism is straight as it aligns the eyelets and the lock loop is fully curled, capturing all three eyelets and securely locking the device in place.

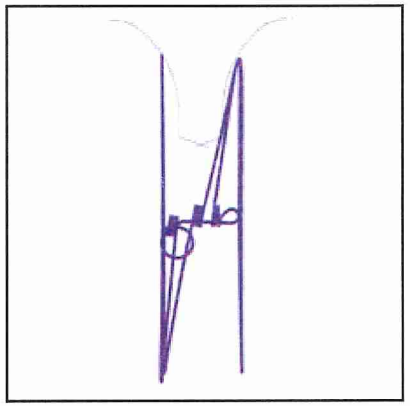


Figure E-4

Septal anatomy, however, seldom allows the Occluder to take on such a theoretically ideal shape after deployment. Variation in the thickness of the septum and the proximity of the defect to other cardiac structures may cause the two discs to appear distinctly non-parallel (Figs. E-5 thru E-7). Apposition to the septum is more important than fluoroscopic appearance. A successful implant should rest in a planar condition relative to the septum. The position can be confirmed by TEE/TOE or by angio. A right atrial contrast injection with observation of the levophase is used to illustrate left and right septal planes and to confirm that the Occluder is well apposed.

Devices should be removed if:

- An excessive shunt persists
- The disks are not apposed to the septum
- The right atrial eyelet was not captured

Keep in mind that the disc-to-disc spacing usually becomes smaller in the first 30 minutes following deployment as the Occluder "settles" into place and further conforms to the cardiac anatomy.

Figure E-5

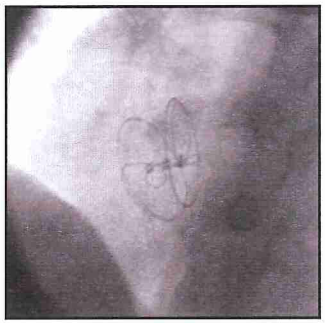


Figure E-6

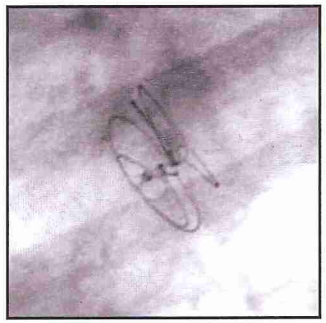
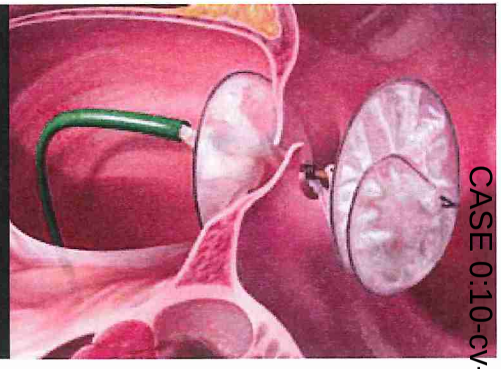


Figure E-7

SELECTED REFERENCES



HELEX SEPTAL OCCLUDER GORE

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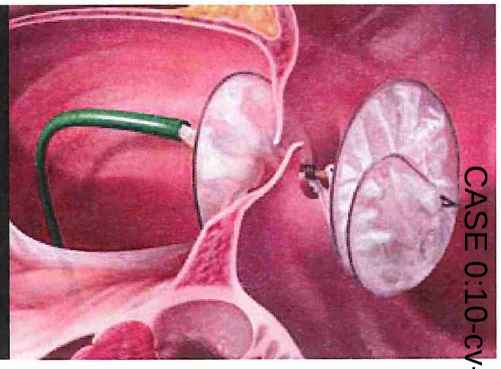
Footnote:
Indicated for closure of ASD and PFO in Europe. Clinical trial underway in the U.S., indicated for ASD only.

⚠ Attention, See Instructions for Use

SELECTED REFERENCES



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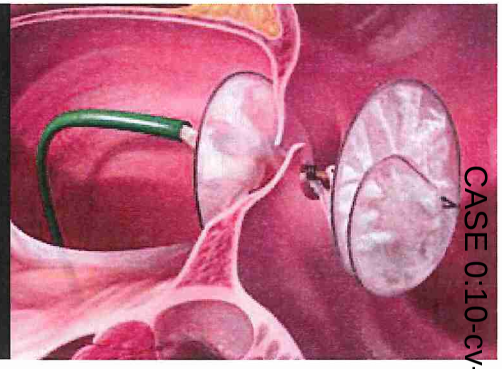
HELEX SEPTAL OCCLUDER GORE

Footnote:
Indicated for closure of ASD and PFO in Europe. Clinical trial underway in the U.S., indicated for ASD only.

⚠ Attention, See Instructions for Use

SELECTED REFERENCES



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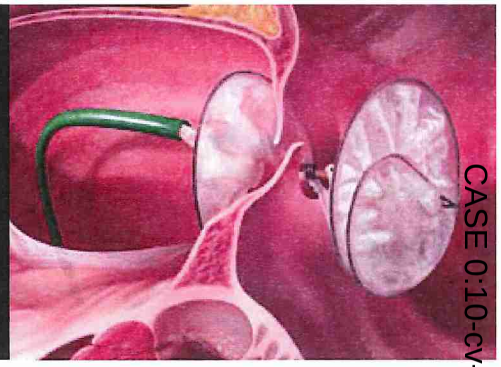

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